

## PROPOSED PREVENTIVE CONTROLS RULE

Docket Number: [FDA-2011-N-0920](#); comments due by May 16, 2013

The U.S. Food and Drug Administration's (FDA's or the Agency's) proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (Preventive Control Rule), requires food facilities to create written plans for how to prevent their products from becoming contaminated as well as how to respond in the event of a contamination or an outbreak.

The proposed rule adds new preventive control provisions to the Agency's current good manufacturing practices (cGMPs) regulations, as required by the Food Safety Modernization Act (FSMA), and largely applies to facilities that are required to register with FDA under the current food facility registration requirements. The proposed Preventive Control Rule also includes requirements for facilities to maintain food safety plans, perform hazard analyses, and institute preventive controls for the mitigation of identified hazards. Facilities would also be required to monitor their preventive controls, verify that preventive controls are effective, take corrective action when necessary, and maintain records documenting these actions.

View the proposed rule at [http://www.ofr.gov/OFRUpload/OFRData/2013-00125\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2013-00125_PI.pdf).

As drafted, the Preventive Control Rule will take effect 60 days after it is published in the *Federal Register*, with staggered compliance dates. Businesses, other than small and very small businesses, will be required to comply with the final rule one year after its publication in the *Federal Register*. Small businesses will be required to comply two years after the final rule's publication in the *Federal Register*, and very small businesses will be required to comply three years after the final rule's publication in the *Federal Register*.

The FDA defined small business and very small business as:

- **Small Businesses**—a business that employs fewer than 500 persons and that does not qualify for an exemption would have to comply two years after publication of the final rule.
- **Very Small Businesses**—Three options are being proposed for the definition of a very small business: less than \$250,000, less than \$500,000, and less than \$1,000,000 in total annual sales of food, adjusted for inflation. FDA is seeking comment on these options. Very small businesses, which would be considered "qualified facilities" and subject to modified requirements for preventive controls, would have to comply three years after publication of the final rule.

The Preventive Control Rule would implement the requirements of the FSMA for covered facilities to establish and implement food safety systems that include hazard analyses and risk-based preventive controls. Specifically, the proposed rule establishes requirements for (1) a written food safety plan, (2) hazard analysis, (3) preventive controls for hazards that are reasonably likely to occur, (4) monitoring, (5) corrective actions, (6) verification, and (7) recordkeeping.

### Covered Facilities

Facilities that manufacture, process, pack, or hold food and that are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (FDCA) are required to comply with the Preventive Control Rule. As a result, any and all parties that are involved in transactions in food must begin with the assumption that they come within the scope of this proposed regulation unless otherwise exempted.

**Qualified facility** means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

- (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
- (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

As in the proposed rule, the economic analysis includes three options for defining a “very small” business – \$250,000 in total annual sales of foods adjusted for inflation, \$500,000 and \$1,000,000. Option one includes 34,600 facilities, representing less .005% of all food produced. Option two adds 45,900 facilities, still less than 1% of food produced, and option three adding 63,500 facilities, which is less than 2% of all food produced in the US. This analysis shows that only a sliver of the food facilities currently in operation will be given the longer window of time to comply with the preventive control rule as proposed.

Farms are not generally covered by the proposed Preventive Control Rule because they are not required to register with FDA under section 415 of the FDCA, unless the farm also manufactures or processes food that is not consumed on the farm or another farm under the same ownership. FDA defines a “farm” as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term “farm” includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

In addition, small or very small farms that conduct certain low-risk packing, holding, manufacturing, or processing activity on the farm (e.g., repacking intact fruits and vegetables or grinding, milling, cracking, or crushing grains) are exempt from the proposed Preventive Control Rule. However, any farm exempt from the Preventive Control Rule may be required to comply with the proposed “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (Produce Rule).

Additionally, facilities that meet one of the following conditions are exempt from the proposed Preventive Control Rule:

1. Small businesses (average annual sales of \$500,000 or less and at least half of their sales to consumers or local retailers or restaurants) and very small businesses (FDA proposes three options for defining a “very small business”: average annual sales below either \$250,000, \$500,000, or \$1,000,000);
2. Facilities subject to the seafood or juice hazard analysis and critical control point (HACCP) requirements;
3. Facilities subject to the low-acid canned food requirements;
4. Facilities that manufacture, process, pack, or hold dietary supplements or alcoholic beverages;
5. Facilities that are solely engaged in the storage of raw agricultural commodities intended for further distribution or processing;
6. Facilities that are solely engaged in the storage of packaged food that is not exposed to the environment; and
7. Facilities that are subject to the proposed Produce Rule.

Facilities that already follow HACCP are exempt or *partially exempt* as provided in the rule. For a company in this category, there are still parts of the rule to heed. For example, ensuring the preventative controls relating to food allergies are met (FSMA is a big step not only in addressing microbiological contamination, but also food allergies).

It is important for companies that determine the exemption or partial exemption fits to understand the second half of the rule. The preventative controls rule would modify the Current Good Manufacturing Practices (CGMP or GMP; 21 C.F.R. Part 110) regulation. The regulations were last revised in 1986.

Generally, CGMP provisions would still apply to facilities that would be exempt from the hazard analysis and risk-based preventive control requirements or that would be subject to modified requirements.

The proposed rule also would establish the conditions under which an exemption granted to a “qualified facility” could be withdrawn, and the procedures that would be followed to withdraw such an exemption.

<b>Type of facility or operation</b>	<b>Hazard Analysis and Risk Based Preventive Control Requirements</b>	<b>Current Good Manufacturing Practices (CGMP)</b>
Certain low-risk manufacturing/processing activities, packing or holding activities that are conducted by small or very small businesses on farms for specific foods. Examples including making jams and jellies and manufacturing honey and maple syrup.	Exempt	Must comply
Foods subject to the low-acid canned food (LACF) regulation. The exemption for facilities producing low-acid canned food applies only to those microbiological hazards addressed by LACF regulation.	Exempt	Must comply
Foods subject to HACCP regulations (seafood and juice)	Exempt	Must comply
Dietary supplements	Exempt	Must comply with dietary supplement CGMPs
Alcoholic beverages at certain alcohol-related facilities, and certain prepackaged food sold in limited quantities along with alcoholic beverages at the same facilities.	Exempt	Must comply
A facility that has food sales averaging less than \$500,000 per year during the last three years. In addition, sales to qualified end users must exceed sales to others. A qualified end-user is either a consumer (in any location), or a restaurant or retail food establishment purchasing the food for sale directly to consumers that is located in the same State or not more than 275 miles away	Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
A very small business. Three options are being proposed to define a very small business: less than \$250,000, less than \$500,000, and less than \$1,000,000 in total annual sales of food, adjusted for inflation.	Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
Activities within the definition of “farm”	Exempt	Exempt
Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment		Must comply

<ul style="list-style-type: none"> <li>• Packaged food for which refrigeration is not required for safety</li> <li>• Packaged food for which refrigeration is required for safety</li> </ul>	<p>If refrigeration is not required for safety, the facility is exempt</p> <p>If refrigeration is required for safety, modified preventive control requirements apply: Requirements concerning temperature controls, including monitoring, verification and records.</p>	
<p>Facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.</p>	<p>Exempt (provided they are solely engaged in such storage)</p>	<p>Exempt</p>
<p>Facilities, such as warehouses, that store raw agricultural commodities that are fruits and vegetables intended for further distribution or processing.</p>	<p>Must comply*</p>	<p>Exempt</p>

### Written Food Safety Plan

The Preventive Control Rule would require each covered facility to create a written food safety plan that identifies and evaluates known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility, including biological, chemical, physical, and radiological hazards, and to conduct an assessment of the severity of the illness or injury if the hazard were to occur. FDA proposes to define the term “hazard that is reasonably likely to occur” as a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

The written food safety plan would need to include, as applicable, the following:

- (1) a hazard analysis,
- (2) preventive controls,
- (3) monitoring procedures,
- (4) corrective action procedures,
- (5) verification procedures, and
- (6) a recall plan.

In addition, a qualified individual would be required to oversee and/or create the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the required reanalysis of the food safety plan. The proposed Preventive Control Rule establishes minimum requirements for the qualified individual. This person would be required to complete training under a standard curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Lastly, the food safety plan would need to be made “promptly” available to FDA upon oral or written request.

### Written Hazard Analysis

The Preventive Control Rule would require the owner, operator, or agent in charge of a facility to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility

to determine whether there are hazards that are reasonably likely to occur. The hazard analysis must contain the justification for whatever conclusion the owner, operator, or agent in charge of the facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, a written hazard analysis would be required under the Preventive Control Rule even if the conclusion of the analysis is that there are no hazards reasonably likely to occur.

The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced, including biological, chemical, physical, and radiological hazards. For example, the Preventive Control Rule would require that the hazard analysis include an evaluation of whether environmental pathogens (e.g., salmonella, L.monocytogenes) are reasonably likely to occur whenever a ready-to-eat (RTE) food is exposed to the environment prior to packaging. In addition, the Preventive Control Rule would require that the hazard evaluation include consideration of the following factors: formulation of the food; the condition, function, and design of the facility and equipment; raw materials and ingredients; transportation practices; manufacturing/processing procedures; packaging and labeling activities; storage and distribution; intended or reasonably foreseeable use; sanitation, including employee hygiene; and any other relevant factors that might potentially affect the safety of the finished food for the intended consumer.

### **Written Preventive Controls for Hazards Reasonably Likely to Occur; Recall Plan**

The Preventive Control Rule would require the owner, operator, or agent in charge of a facility to identify and implement preventive controls, including at critical control points, to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FDCA or misbranded under section 403 of the FDCA. The procedures, practices, and processes for preventive controls must include the following, as appropriate:

- process controls;
- employee training;
- environmental monitoring;
- food allergen controls;
- sanitation controls, including procedures for the prevention of cross-contact and cross-contamination;
- a recall plan;
- cGMPs policies;
- and supplier verification activities.

**The application of the preventive controls requirements would be required only in cases where facilities determine that hazards are reasonably likely to occur.**

### **Written Recall Plan**

The Preventive Control Rule would also require that preventive controls include a recall plan for food in which there is a hazard reasonably likely to occur. The recall plan would need to include procedures that describe the steps to be taken, and assign responsibility for taking those steps, in order to perform the following actions: (1) directly notify the direct purchasers of the product being recalled and provide information for returning or disposing of the affected food; (2) notify the public about any hazard presented by the food when appropriate to protect public health; (3) conduct effectiveness checks to verify that the recall is carried out; and (4) appropriately dispose of the recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food).

### **Monitoring**

The Preventive Control Rule would require an owner, operator, or agent in charge of a facility to monitor the performance of the established preventive controls. The proposed rule states that “monitor” means “to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in observation.” According to FDA, examples of monitoring activities include visual observation and measurement of temperature, time, and pH and moisture levels. The proposed rule does not specify a single monitoring frequency applicable to all facilities and processes but instead requires monitoring with “sufficient frequency” to ensure that the preventive controls are consistently performed. The Preventive Control Rule would also require that all monitoring of preventive controls be documented in records subject to verification and review.

## Corrective Actions

The Preventive Control Rule would require that an owner, operator, or agent in charge of a facility establish and implement written corrective action procedures to take if preventive controls are not properly implemented. The rule would also require that corrective action procedures describe the steps to be taken to ensure the following: that appropriate action is taken to identify and correct a problem with the implementation of a preventive control to reduce the likelihood that the problem will recur; all affected food is evaluated for safety; and all affected food is prevented from entering into commerce if the owner, operator, or agent in charge of the facility cannot ensure that the affected food is not adulterated or misbranded. Lastly, all corrective actions would need to be documented in records that are subject to verification and review.

## Verification

The Preventive Control Rule would require that an owner, operator, or agent in charge of a facility conduct certain verification activities of its food safety plan, including validation of a subset of the preventive controls, verification that monitoring is being conducted, verification that appropriate decisions about corrective actions are being made, and verification that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur.

Verification would include activities such as collecting and evaluating scientific and technical information to determine whether the preventive controls will effectively control the hazards that are reasonably likely to occur, but it does not need to address food allergen and sanitation controls and the recall plan. Validation would need to occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production (e.g., for controls that require live production for validation).

The Preventive Control Rule would also require that validation of the preventive controls be performed whenever a reanalysis of the food safety plan reveals the need to do so. In addition, all preventive controls established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis. Establishing the scientific and technical basis is a validation activity, regardless of whether the preventive control is established in the facility's initial food safety plan or as a result of reanalysis of the food safety plan.

The Preventive Control Rule would further require the facility to conduct a reanalysis of the food safety plan at least once every three years; whenever a significant change is made in the activities of the facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard; whenever the owner, operator, or agent in charge becomes aware of new information about potential hazards associated with the food; whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and whenever a preventive control is found to be ineffective.

Details of what evidence will document sufficient verification under the Preventive Control Rule are a critical factor and likely to be the subject of much comment. In addition, verification activities must be documented in records that are subject to verification and review.

## Recordkeeping

The Preventive Control Rule would require an owner, operator, or agent in charge of a facility to maintain records documenting the following: (1) the written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan; (2) the monitoring of preventive controls; (3) corrective actions; (4) verification, including validation, monitoring, corrective actions, calibration of process monitoring and verification instruments, records review, and reanalysis; and (5) training for the qualified individual who wrote or oversaw the formation of the facility's food safety plan. These records must be maintained at the plant or facility at which they were prepared for no less than two years. Records could be moved to off-site storage after six months following the date that the record was made if such records can be retrieved and provided on-site within 24 hours of a request for official review. However, the food safety plan would be required to remain on-site.

The Preventive Control Rule would further require that records be kept as original records, true copies (such as

photocopies, photographs, scanned copies, etc.), or electronic records (electronic records would be considered to be kept on-site if they are accessible from an on-site location). In addition, records would be required to contain the actual values and observations obtained during monitoring, as opposed to, for example, simply marking the measurements as “satisfactory” or “unsatisfactory.” Moreover, records would be required to be accurate and legible, be created concurrently with performance of the activity documented, and be as detailed as necessary to provide a history of the work performed. Lastly, the Preventive Control Rule would require that the records include the name and location of the plant or facility; the date and time of the activity documented; the signature or initials of the person performing the activity; and, where appropriate, the identity of the product and production code, if any.

### **Effective and Compliance Dates and Definitions for Small and Very Small Businesses**

FDA is proposing the following effective and compliance dates for businesses subject to the proposed rule. Recognizing that small and very small businesses may need more time to comply with the requirements, the compliance dates are adjusted accordingly.

- **Effective Date:** 60 days after the final rule is published
- **Compliance Dates:**
  - **Small Businesses**—a business that employs fewer than 500 persons and that does not qualify for an exemption would have to comply two years after publication of the final rule.
  - **Very Small Businesses**—Three options are being proposed for the definition of a very small business: less than \$250,000, less than \$500,000, and less than \$1,000,000 in total annual sales of food, adjusted for inflation. Very small businesses, which would be considered “qualified facilities” and subject to modified requirements for preventive controls, would have to comply three years after publication of the final rule.
  - **Other Businesses**—a business that is not small or very small and does not qualify for an exemption would have to comply one year after publication of the final rule.

### **How do I comment on the proposed rules?**

These are proposed draft rules and not final regulation. Stakeholders are encouraged to comment on aspects of the rules they object to or do not understand.

**Submit either electronic or written comments by May 16, 2013.**

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Insert the docket number into the “search” box and follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

All submissions received must include the Agency name and Docket No. FDA-2011-N-0920; and Regulatory Information Number RIN 0910-AG36 for this rulemaking.